

### **Remarks**

Claims 1-35 are pending in this application and Applicants acknowledge that claims 1-8, 14, 16-18, 22, 23, and 32 are currently under examination (claims 9-13, 15, 19-21, 24-31, and 33 have been withdrawn from current consideration). Applicants also request examination of added claims 34-35. The 3-month shortened statutory period for filing a response to the outstanding Office action ended January 16, 2004. Applicants therefore request a one-month extension to respond, making a response due by February 17, 2004 (February 16, 2004, was a Federal Holiday). A check for \$146 is enclosed to cover the extension fee and the fees for the additional claims.

In response to the previous Restriction Requirement Applicants elected (with traverse) the species of an oral dosage of a high molecular weight, lipophilic, bioactive agent, comprising an antioxidant, a lipid matrix, and resveratrol. Applicants reserve the right to have additional species examined upon allowance of a generic claim.

This Office action alleges that Applicants' claims currently under examination are anticipated, obvious, and/or indefinite. Applicants traverse these allegations. Applicants also have amended claims 1, 6, 18, and 22 and added claims 34 and 35.

### **Rejections under 35 U.S.C. § 102 (a) and (e)**

This Office action alleges that Applicants' claims 1-8, 14, and 22 are anticipated under § 102(a) by PCT International Publication No. WO 01/52822 by Chopra ("the PCT publication") and under § 102(e) by U.S. Patent No. 6,300,377 to Chopra ("the '377 patent"), collectively "the Chopra publications."<sup>1</sup> Applicants disagree.

#### **Claim 1**

The Chopra publications disclose a composition that requires coenzyme Q, a surfactant, a triglyceride, and a mono-, di-, or tri- glyceryl ester. (Column 2, lines 1-14.) But Applicants' claimed composition does not contain a surfactant. Indeed, Applicants warned that inclusion of a surfactant could cause adverse side-effects in subjects consuming the composition, such as diarrhea. (Application, page 5, lines 23-24.) Applicants have amended claim 1 to include the preamble

---

<sup>1</sup> Though the '377 patent and the PCT publication are not identical, their disclosures are similar. For ease of reference Applicants cite only to the '377 patent in this response as was done in the Office action.

“consisting essentially of”. This preamble excludes a surfactant from the claimed composition because a surfactant element would materially change the invention, namely by causing unwanted side-effects.

Because Applicants’ claim 1 excludes a required constituent of the composition disclosed in the Chopra publications, the Chopra publications do not disclose a composition that anticipates claim 1. Accordingly, Applicants request withdrawal of this rejection.

#### Claims 2-8, 14, and 22

Each of these claims depends from allowable claim 1. Therefore, each of these claims is allowable. These claims are further allowable as a result of their additional unique features. Accordingly, Applicants request withdrawal of the rejections of claims 2-8, 14, and 22.

#### Claim 34

New claim 34 also depends from claim 1 and is allowable for the reasons discussed above in relation to claims 2-8, 14, and 22.

#### Claim 35

New claim 35 is previous claim 1 rewritten to include the limitation that the claimed composition does not contain a surfactant. Claim 35 is allowable because it excludes a required element of the composition disclosed in the Chopra publications.

#### **Rejections under 35 U.S.C. § 103(a)**

This Office action alleges that Applicants’ claims 1-8, 14, 16-18, 22, 23, and 32 are obvious under § 103(a) in view of the Chopra publications. Applicants traverse.

#### Claim 1

There is no suggestion or motivation in the Chopra publications to exclude surfactants from the composition disclosed in the Chopra publications to make Applicants’ claimed composition. Indeed, excluding a surfactant would contravene the teaching in the Chopra publications that a surfactant must be included for enhanced bioavailability.

As noted above, the Chopra publications disclose a composition that requires a surfactant. (Column 2, lines 1-14.) The Chopra publications require the surfactant in order to “promote the solubility of the ubiquinone.” (Column 3, lines 2-3.) Such solubility of the ubiquinone is an important aspect of the composition disclosed in the Chopra publications as illustrated by the fact that an “object of the [Chopra] invention” was to provide “enhanced bioavailability” of coenzyme Q. (Column 1, lines 54-57.) Claim 1 is not obvious because not including a surfactant in the claimed composition would contravene the explicit teaching of the Chopra publications.

While the composition disclosed in the Chopra publications requires a surfactant for its utility, Applicants’ claimed composition excludes surfactants. Instead of a surfactant, Applicants’ composition includes a polyphenol because Applicants discovered that “polyphenolic compounds can increase the absorption of a large, high molecular weight, orally ingested, lipophilic bioactive agent or combination of bioactive agents when these materials are simultaneously administered from a triglyceride matrix.” (Application, page 7, lines 16-19.) The Chopra publications nowhere suggest or motivate the exclusion of a surfactant and the requirement of a polyphenol, and, in fact, teach against the exclusion of surfactants.

Indeed, the composition disclosed in the Chopra publications only optionally includes an active agent (column 2, line 19) which may include resveratrol (column 6, lines 42-65.) (Resveratrol is a polyphenol as claimed in Applicants’ claim 1.) Moreover, the Office action admits “Chopra does not expressly teach that the polyphenol comprising his composition improves gastrointestinal absorption of the bioactive agent.” (Office action, p. 7.) Thus, one of ordinary skill in the art would not have found it obvious to exclude the surfactant from the composition disclosed by the Chopra publications and instead use a polyphenolic compound to increase bioavailability of a bioactive agent.

Because the Chopra publications teach against excluding the surfactant from the disclosed composition and provide no motivation to require a polyphenol, Applicants’ claimed composition that “consists essentially of” recited elements that do not include a surfactant is not obvious over the Chopra publications. Accordingly, Applicants request withdrawal of this rejection.

Claims 2-8, 14, 16-18, 22, 23, and 32

Each of these claims depends from allowable claim 1. Therefore, each of these claims is allowable. These claims are further allowable as a result of their additional unique features. Accordingly, Applicants request withdrawal of the rejections of claims 2-8, 14, 16-18, 22, 23, and 32.

Claim 34

New claim 34 also depends from claim 1 and is allowable for the reasons discussed above in relation to claims 2-8, 14, and 22.

Claim 35

New claim 35 also excludes surfactants. It is allowable for the reasons discussed above in relation to claim 1.

**Rejections under 35 U.S.C. § 112, second paragraph**

This Office action alleges that claims 6, 7, 15, 16, 18, and 22 are indefinite under § 112, second paragraph. Applicants have amended claims 6 and 18 as suggested. Applicants traverse the rejections of claims 7, 15, 16, and 22.

Claim 7

This Office action lists this claim as an indefinite claim, but makes no specific allegations as to the allegedly indefinite language. Accordingly, Applicants request that this rejection be withdrawn.

Claim 15

Contrary to the allegation in this Office action, the phrase “wherein the polyphenol comprises Polygonum cuspidatum extract” is not indefinite. Applicants explained in the specification that the polyphenol includes “any ingredient containing two or more hydroxyl groups on a phenyl ring.” (Page 10, lines 15-17.) Thus, one of skill in the art would recognize that the term “polyphenol” refers to a composition ingredient containing one or more polyphenolic compounds. As the Office action notes, Polygonum cuspidatum extract is an ingredient that “comprises resveratrol,” a polyphenolic

compound. (Office action, p. 4.) Accordingly, claim 15 is not indefinite and Applicants request withdrawal of this rejection.

#### Claim 16

Contrary to the allegation in this Office action, the phrase “wherein the polyphenol comprises resveratrol” is not indefinite. The fact that resveratrol is a polyphenol does not render this claim indefinite. Applicants explained that the polyphenol could comprise one or more polyphenols (column 10, line 14), noting that “a polyphenolic compound (including combinations of polyphenolic compounds)” are used to improve bioavailability (emphasis added). Claim 16 simply claims a composition where the polyphenol includes resveratrol. The open ended “comprises” language indicates simply that other polyphenols also may be present. One of ordinary skill in the art would not be confused by the open ended language given the explanation in the specification that the recited polyphenol may contain more than one polyphenolic compound. Accordingly, claim 16 is not indefinite and Applicants request withdrawal of this rejection.

#### Claim 22

This Office action alleges that the percentages recited in this claim are indefinite because one of ordinary skill in the art would not know whether the percentages are by weight or by volume. However, Applicants refer in the specification to amounts of the constituents of the composition in percentage by weight (page 15, line 23). Thus, one of ordinary skill in the art would interpret claim 22 to refer to percentages by weight. Nevertheless, Applicants have amended claim 22 to clarify that the recited percentages are by weight. Accordingly, claim 22 is not indefinite and Applicants request withdrawal of this rejection.

#### Conclusion

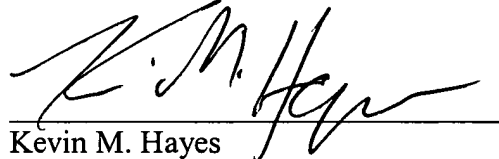
Based on the foregoing amendments and remarks, Applicants submit that this application is in condition for allowance and such action is respectfully requested. If the Examiner believes that any

further action would place this application in better condition for allowance, the Examiner is invited to telephone the undersigned at (503) 226-7391.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

By

  
Kevin M. Hayes  
Registration No. 54,158

One World Trade Center, Suite 1600  
121 S.W. Salmon Street  
Portland, Oregon 97204  
Telephone: (503) 226-7391  
Facsimile: (503) 228-9446